

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
CASE NO. 15-cv-09841-DLC**

SHANNON MAHONEY, individually and
on behalf of herself and all others similarly
situated,

Plaintiff,

v.

CLASS ACTION

ENDO HEALTH SOLUTIONS, INC., a Delaware corporation; ENDO PHARMACEUTICALS, INC., a Delaware corporation; GENERICS INTERNATIONAL (US PARENT), INC., a Delaware corporation d/b/a Qualitest Pharmaceuticals; GENERICS INTERNATIONAL (US), INC., a Delaware corporation; GENERICS BIDCO I, LLC, a Delaware limited liability company; GENERICS BIDCO II, LLC, a Delaware limited liability company; GENERICS INTERNATIONAL (US HOLDCO), INC., a Delaware corporation; GENERICS INTERNATIONAL (US MIDCO), INC., a Delaware corporation; and VINTAGE PHARMACEUTICALS, LLC, a Delaware limited liability company,

JURY TRIAL
DEMANDED

Defendants.

/

**UNOPPOSED MOTION FOR PRELIMINARY APPROVAL OF THE SETTLEMENT
BETWEEN PLAINTIFF AND THE DEFENDANTS AND AUTHORIZING THE
DISSEMINATION OF NOTICE TO THE SETTLEMENT CLASS**

Plaintiff Shannon Mahoney moves for an order preliminarily approving a proposed settlement with the Defendants (“Settlement”)¹, certifying the Class, and authorizing the dissemination of notice of the settlement to the Class members. If approved, the Settlement will resolve all claims against the Defendants related to the fluoride content of the Multi-Vitamin with

¹ The Settlement is memorialized in the October 19, 2016 settlement agreement attached as Exhibit 1 to this Motion (“Settlement Agreement”). Unless otherwise indicated, all defined terms in this memorandum shall have the same meaning as in the Settlement Agreement.

Fluoride Chewable Tablets (“Tablets”). For the reasons set forth herein, the Plaintiff respectfully requests that the Court grant her motion for an Order: (i) preliminarily approving the Settlement; (ii) certifying a settlement Class; (iii) appointing Ms. Mahoney as Class Representative; (iv) appointing David M. Buckner, Seth E. Miles, and Brett E. von Borke of Buckner + Miles and Ryon McCabe and Robert C. Glass of McCabe Rabin as Class Counsel; (v) approving the form and manner of notice to the Class; and (vi) setting the hearing at which the Court will consider final approval of the Settlement (“Settlement Hearing”).

I. INTRODUCTION

Subject to Court approval, the Plaintiff, on behalf of herself and the Class, have agreed to settle the Class’ claims with the Defendants for \$15,500,000. This represents a recovery of roughly 50% of the revenue that the Defendants received from the sale of Tablets from the Class as defined below. The Plaintiff respectfully submits that the proposed Settlement is an excellent result for the Class and satisfies the standard for preliminary approval under Rule 23 of the Federal Rules of Civil Procedure. The Settlement is the result of comprehensive, vigorous, and arms-length negotiations, with significant involvement over the course of two separate in-person mediations from retired United States District Court Judge Barbara Jones, in addition to numerous telephonic negotiating sessions among the parties over the course of several months. The Settlement is fair and reasonable considering the substantial benefit to the Class and the significant litigation risk that the Class might not prevail at certification or at trial. In this regard, the Settlement reflects the judgment of Plaintiff’s counsel based on their extensive experience in complex litigation, independent and corroborative evaluations of the ability to succeed at class certification and at trial, and informed through the settlement discussions about the relative strengths and weaknesses of Plaintiff’s and Defendants’ cases.

While Plaintiff's counsel was confident in their ability to certify a litigation class and prevail at trial, Plaintiff's counsel firmly believes the Settlement is in the best interests of the Class. At the Settlement Hearing for final approval, the Court will have before it more extensive motion papers submitted in support of the Settlement and proposed distribution of funds, and will at that time make a determination as to whether the Settlement is fair, reasonable, and adequate under all of the circumstances of this case. At this juncture, the Plaintiff requests only that the Court preliminarily approve the Settlement so that Counsel may provide notice to the Class and the Settlement Hearing may be scheduled.

II. FACTUAL BACKGROUND

A. THE PLAINTIFF'S ALLEGATIONS IN THIS LAWSUIT

For communities that do not have fluoridated drinking water, the American Dental Association ("ADA") and the American Academy of Pediatrics ("AAP"), recommend that children receive daily dietary supplements containing fluoride ion in the amount of 0.25 mg, 0.5 mg, or 1.0 mg. *See* First Amended Complaint ("FAC") [D.E 48 at ¶ 19]. Plaintiff alleges that the Defendants manufactured the Tablets which purported to deliver these precise dosages of fluoride ion. *See* [D.E. 48 at ¶ 24]. However, from 2007 through 2013, the Defendants manufactured Tablets that delivered less than one half of the amount of fluoride ion claimed on the label. [D.E. 48 at ¶ 31]. As a result, children who were prescribed the Tablets in accordance with the recommendations of the ADA-AAP Guidelines and consumed one Tablet per day, as the product labeling instructed, received only 44% of the fluoride ion recommended by the ADA-AAP. [D.E. 48 at ¶ 39]. The Plaintiff and the members of the Class paid for the Tablets and were damaged thereby. [D.E. 48 at ¶ 5, 41, 49].

Defendants in their litigation with the United States government, admitted that instead of

using 2.2 mg of sodium fluoride as an ingredient to deliver 1 mg of fluoride ion for the 1 mg Tablet, they used only 1 mg of sodium fluoride. Similarly, instead of using 1.1 mg of sodium fluoride for the 0.5 mg Tablet and 0.55 mg of sodium fluoride for the 0.25 mg Tablet, Defendants used 0.5 mg of sodium fluoride and 0.25 of sodium fluoride, respectively. *See* [D.E. 48 at ¶ 33]. As a result, as alleged in the Complaint, hundreds of thousands of children ingested sub-potent Tablets. The Defendants deny these allegations.

B. PROCEDURAL BACKGROUND

The Plaintiff filed her class action Complaint against the Defendants on December 17, 2015. [D.E. 1]. On February 24, 2016, the Defendants moved to dismiss Plaintiff's class action Complaint. [D.E. 38, 39]. On February 26, 2016, the Court held a scheduling conference. [D.E. 42]. At that hearing, the Court ordered the parties to attend an early mediation and stayed all discovery in the lawsuit until the parties mediated. [*Id.*] The Court also told the Plaintiff that if she wished to amend the complaint to address any of the assertions in the Defendants' motion to dismiss, she should do so now.

Plaintiff filed her First Amended Class Action Complaint on March 18, 2016. [D.E. 48]. On April 19, 2016, the Defendants filed their Motion to Dismiss Plaintiff's First Amended Class Action Complaint. [D.E. 63, 64]. The Plaintiff filed her response on May 16, 2016 [D.E. 70], and the Defendants filed their reply on June 2, 2016. [D.E. 73]. The Court granted in part and denied in part Defendant's Motion to Dismiss on July 20, 2016. [D.E. 79].

The parties agreed to use retired United States District Court Judge Barbara Jones as their mediator. The parties scheduled their initial mediation for April 20, 2016. In advance of the mediation, counsel for both parties engaged in several telephonic settlement discussions. In addition, both parties submitted confidential mediation briefs to Judge Jones. On April 20, 2016,

the parties attended an all-day mediation with Judge Jones. However, the case was not resolved at that mediation. Counsel for the parties continued to have numerous telephonic settlement discussions even as they prepared to litigate the case. The parties negotiated and agreed to a number of proposed orders to facilitate this litigation, including an ESI protective order governing the production of confidential documents [D.E. 45], and a HIPAA protective order [D.E. 46].

As a result of the ongoing settlement discussions, counsel for the parties believed it would be beneficial to schedule a second all-day mediation with Judge Jones. The parties agreed to mediate on July 19, 2016. However, prior to that mediation, counsel for the parties had numerous telephonic settlement discussions to ensure additional progress could be made at the July 19, 2016 mediation. Among the matters discussed during these calls was the appropriate measure of damages. Defendants provided Plaintiff with sales and other data to enable Plaintiff's counsel to conduct their own damages analysis. Counsel for the parties attended the all-day mediation with Judge Jones on July 19, 2016. Despite considerable efforts on both sides, the parties were unable to reach an agreement. Once again the matter did not resolve, but the parties, with the encouragement of Judge Jones, agreed to keep talking. The parties continued negotiating during this time.

From July 19, 2016 to August 17, 2016, counsel for the parties had many telephonic discussions in an effort to reach a settlement. On August 17, 2016, the parties agreed to the material terms of a settlement and informed the Court about the settlement on August 18, 2016. Throughout the months of August, September, and October, counsel for both parties spent considerable time negotiating, drafting, and finalizing the Settlement Agreement. The parties signed the Settlement Agreement on October 19, 2016. The Settlement was the result of dynamic,

robust negotiations conducted by experienced counsel on both sides. A positive outcome was neither assured nor easily obtained.

The Settlement of this lawsuit was the result of intense arms-length negotiations involving a former United States District Court Judge and hundreds of hours of settlement negotiations. The Settlement required extensive work on both sides and was only obtained because of the substantial effort expended by counsel for both parties. The Settlement Agreement reflects and addresses the complexity of the issues in this case and the amount of effort required to negotiate its resolution.

In response to this Court's Order, the Plaintiff, on August 26, 2016, filed a letter with the Court outlining the proposed notice program and a plan to identify the members of the Class. [D.E. 82]. On August 29, 2016, the Court entered an Order requesting additional information regarding the identification and notice program. [D.E. 83]. The Plaintiff on September 9, 2016, filed another letter with the Court providing additional information regarding the identification and notice program. [D.E. 84]. The Court on September 12, 2016, authorized Plaintiff to proceed with the plan. [D.E. 85]. On October 21, 2016, Plaintiff filed her Motion for Preliminary Approval of the Settlement. [D.E. 90].

C. SUMMARY OF THE SETTLEMENT TERMS

The Settlement's terms are detailed in the Agreement attached as Exhibit 1. The following is a summary of the material terms of the Settlement.

1. The Settlement Class

The Class is an opt-out class under Rule 23(b)(3) of the Federal Rules of Civil Procedure. The Class is defined as:

All persons and entities who paid for Multi-Vitamin with Fluoride Tablets between October 31, 2007, and December 31, 2015, excluding (a) government entities who were parties to the settlement in *United States v. Vintage Pharmaceuticals, LLC, et al.*, Case No. 13 civ. 1506 (DLC), (b) Defendants and their officers, directors, agents and employees,

and (c) all persons and entities that acquired Multi-Vitamin with Fluoride Tablets for sale to others.

2. Monetary Relief For The Benefit Of The Class

The Settlement requires the Defendants to pay \$15,500,000 to the Class, which will be deposited into an Escrow Account (“Settlement Fund”).² All fees, costs, and expenses of notice and administration of the Settlement (including the fees and costs incurred in the calculation, verification, and payment of distributions from the Settlement Fund to Class members) along with attorneys’ fees will be deducted from the Settlement Fund. The amount of the distribution from the Settlement Fund to which each Class member is entitled will be determined by the Claims Administrator based on the information provided by several sources, including third-party payors (“TPPs”), pharmacy benefit management companies (“PBMs”), and the Class members when they file their claims. The amount paid to each Class member will depend in part on the number of claims filed. Each Class member will receive their *pro rata* share of the Settlement Fund.

The amount of the Net Settlement Fund attributable to uncashed or returned checks or other payments sent by the Settlement Administrator will remain in the Settlement Fund for at least six months from the date that the first distribution check is mailed by the Settlement Administrator, during which time the Settlement Administrator will make a reasonable effort to locate intended recipients of Settlement Funds whose payments could not be made. The Settlement Administrator will make one attempt to re-mail or re-issue those payments. Any funds that remain in the Settlement Fund after one year plus 30 days from the date the last settlement fund payments are

² The funds will be deposited in the Escrow Account in stages. The first deposit of \$400,000 will be deposited within 30 days of preliminary approval, and will be used to fund the first part of the notice program. The second deposit, of \$15,100,000, will be made within 30 days of Final Approval or January 15, 2017, whichever is later. Defendants have agreed that if additional funds are required to pay for notice or claims administration prior to Final Approval, they will confer with Plaintiff’s counsel and fund those reasonable amounts.

mailed by the Administrator, will be distributed through a *cy pres* program, with the Court's approval. If and when that occurs, Plaintiff's counsel will propose a *cy pres* program and present it to the Court for approval.

3. The Plaintiff And The Defendants Sign Mutual Releases

In exchange for the benefits conferred by the Settlement, after final approval of the Settlement, all Class members who do not opt-out, and the Defendants, will be deemed to have released each other from claims relating to the subject matter of this lawsuit.

4. The Notice Program

The proposed notice and settlement administrator is AB Data. The notice program is designed to provide the best notice practicable, and it is tailored to identify and provide notice to as many of the Class members as possible. The notice program is reasonably calculated under the circumstances to apprise the Class of the pendency of the lawsuit, class certification, the terms of the Settlement, Class Counsel's fee application and request for a service award for the named Plaintiff of \$10,000, and the Class members' rights to opt-out of the Class or object to the Settlement. The notice and notice program constitute sufficient notice to all persons entitled to notice and satisfy all applicable requirements of law including, but not limited to, Federal Rule of Civil Procedure 23 and the Constitutional requirement of due process.

The notice program will use three different methods to provide notice: (1) direct mail postcard notice ("Mailed Notice") to all identifiable Class members; (2) publication notice ("Published Notice") designed to reach those Class members for whom direct mail notice is not possible or successful; (3) and the "Long Form Notice" with more detail than the direct mail or publication notices, that will be available on the Settlement website (the address of which will be set out in the direct mail and publication notices and on a toll-free hotline). The notice program is

designed to provide the Class with important information regarding the Settlement and their rights, including a description of the material terms of the Settlement; a date by which Class members may exclude themselves from or opt-out of the Class; a date by which Class members may object to the Settlement; the address of the Settlement Website at which Class members may access the Agreement and other relevant documents and information; and the toll-free hotline where Class members may learn more about the Settlement and leave a message for the Claims Administrator. In addition to the information described above, the Long Form Notice will also describe the procedure Class members must use to opt-out of or object to the Settlement. All opt-outs and objections must be received by the last day of the Opt-Out Period.

(a) The Mailed Notice Program

In order to ensure that notice is provided to the largest number of identifiable consumer Class members, Plaintiff's counsel is proposing a multi-step mailed notice program targeting different members of the Class. First, in order to identify the largest number of Class members so that counsel can provide direct notice to them or pay them directly from the Settlement Fund, Plaintiff's counsel has served subpoenas on the seven largest Pharmacy Benefits Manager ("PBMs") and the nineteen largest pharmacy chains in the United States, to obtain electronic files of the names and addresses of the Class members that purchased the Tablets as well as information concerning those purchasers' expenditures on the Tablets during the Class period. The seven PBMs are Express Scripts, CVS Caremark, OptumRx, Catamaran, Prime, Humana, and Medimpact. These PBMs account for more than 90% of the PBM market, based on total equivalent prescriptions filled. Most of the TPPs rely on PBMs to administer their prescription drug benefits program. A typical PBM administers the payments by the TPPs to individual pharmacies. This requires PBMs to maintain a computer database that records every transaction by an individual in a health plan of the PBMs service, typically using a multi-digit numeric code known as an NDC

number. Plaintiff's counsel has identified the fifteen NDC numbers of the affected Tablets, and is using them both as part of the subpoena process (to minimize the burden on third-parties), and ultimately as the method for identifying and isolating the transactions causing damages to the members of the Class.

Simultaneous with the issuing of the subpoenas to the seven largest PBMs, Plaintiff's counsel issued subpoenas to the nineteen largest providers of retail pharmacy services in the United States (*e.g.*, Walmart, Walgreens, CVS) to obtain electronic files of the names and addresses of Class members that purchased the Tablets as well as information concerning those Class members' expenditures on the Tablets during the Class period. This data should include both insureds who received their prescriptions for the Tablets filled at these providers as well as those Class members who paid for the Tablets in cash and did not utilize insurance.

The Claims Administrator, AB Data, will provide postcard notice to the TPPs within 21 days of entry of an Order granting preliminary approval of the Settlement, in substantially the same form as attached as Exhibit 2. The Claims Administrator has, through its work on other notice programs in litigation involving pharmaceuticals, compiled a database of TPPs using membership listings and existing databases from publicly available sources including the United States Department of Labor Form 5500 filings and the Pharmacy Benefits Management Institute. That database includes approximately 42,000 unique TPP contacts. The notice to the TPPs will, in addition to providing them with information about the Settlement and what they need to do to file a claim, also request as part of the claims process the electronic files of the names and addresses of Class members who received the Tablets as well as information concerning those Class members' expenditures on the Tablets. This will provide data additional to that received from the

PBMs and pharmacies, depending on the number of responses and level of compliance with these requests by the TPPs.

After the Claims Administrator receives from the TPPs the electronic files of the names and addresses of Class members who purchased the Tablets as well as information concerning those Class members' expenditures on the Tablets, it will consolidate that data with the information received from the PBMs and the pharmacies and de-duplicate it to eliminate multiple references to the same consumer/insured. Thereafter, the Claims Administrator will send out a second round of postcard notice, which is attached as Exhibit 3, to those Class members identified from these lists. This second notice will occur after the first postcard notice is provided to the TPPs is completed and will occur as quickly as the data is compiled.

(b) The Published Notice Program

The Claims Administrator shall administer the Published Notice Program and will publish notice in the form attached as Exhibit 4. The Published Notice will be run in the following magazines: (1) Better Homes and Gardens; (2) Family Fun; (3) Parents; (4) Parents Latina; (5) People; and (6) National Underwriter: Life and Health. These magazines have a circulation that effectively cover the United States and will adequately supplement the postcard notice that the Class members will receive. In addition, the Claims Administrator will run "right-rail advertisements" about the Settlement on Facebook and "banner advertisements" on Google Network, together resulting in 85,000,000 impressions. Each of those advertisements will include a link to the case-specific website and the toll-free telephone number discussed in the section below. Finally, information about the Settlement will be disseminated on PR Newswire through US1 and Hispanic Newswire.

(c) The Settlement Website and Toll-Free Hotline

The Claims Administrator will create a case-specific website (www.fluoridetabletssettlement.com) that contains information about the lawsuit. That website will be used by the Claims Administrator as a means for Class members to obtain notice of, and information about, the Settlement. The Settlement Website will include hyperlinks to the Settlement, the Long-Form Notice substantially in the form attached as Exhibit 5, the Preliminary Approval Order, the Amended Complaint, and other relevant documents. These documents will remain on the Settlement Website at least until Final Approval.

In addition, the Claims Administrator will create a pre-recorded toll-free hotline that will contain the information on the Long-Form notice. The toll-free telephone number will be 1-800-983-6133. This will allow Class members to obtain additional information about the Settlement. At the end of the recording, Class members will be informed that they can leave a message and the Claims Administrator will timely return all messages left.

(d) Opt-Out Form

For any individual that wants to opt-out of the Settlement, they can provide notice to Plaintiff's counsel as prescribed in the Long-Form Notice. For any institution that wants to opt-out of the Settlement, they will be required to fill out the Institutional Opt-Out form attached as Exhibit 6.

5. Distribution Formula

First, the Claims Administrator will utilize the data obtained from the pharmacy chains, third-party payors and pharmacy benefits administrators to, where possible, identify individual consumer Class members, their addresses, and the total amount of money each of them spent to purchase the Tablets during the Class Period ("Identified Claims"). The Claims Administrator will pay the Identified Claims (*pro rata*, as set forth below). No claim form will be required for

these payments. Second, there will be a claims process for individuals and entities to submit claims for payment (“Submitted Claims”). All consumer Submitted Claims up to \$250 will be paid (*pro rata*) whether the Class member provides supporting documents or not, unless the claim would create a payment that is duplicative of an Identified Claim. For consumer Submitted Claims above \$250, consumer claimants will be required to submit documentation supporting their claim, and if they do so, they will be paid (*pro rata*), unless the claim would create a payment that is duplicative of an Identified Claim. The consumer claims form is attached as Exhibit 7. For Submitted Claims by entities including third-party payors, health insurers, and other Submitted Claims for payments made on behalf of more than one natural person, the entity submitting the claim will be required to provide information supporting their claim, as set forth in the claim form attached as Exhibit 8. Entities including third-party payors, health insurers, and other non-natural person Class members will also be requested to provide information about the individual insureds for whom they paid for Tablets, including name, address, and payments made by the insured. All Submitted Claims and Identified Claims will be paid on a *pro rata* basis, as a percentage of total allowed, submitted and identified Claims, up to 100% of each claim made.

6. Timing

If the Court grants preliminary approval, postcard notice to the TPPs will be mailed out within 21 days from the entry of the order granting preliminary approval. Direct mail notice to consumers will occur on a rolling basis as Plaintiff’s counsel receives consumer data from third-party sources. The Claims Administrator will provide direct mail notice *via* postcard only to consumers whose mailing addresses Plaintiff’s counsel is able to obtain prior to March 1, 2017. Prior to March 1, 2017, all Class members will receive notice *via* Publication Notice. Publication Notice will run in the magazines identified above, disseminated on certain newswires, and advertised on Facebook and Google Network. Plaintiff proposes that all objections and opt-out

notices must be postmarked no later than April 17, 2017. The proposed deadline by which all claims must be filed online or postmarked is April 17, 2017. The proposed deadline for filing a Notice of Intention to Appear at the Final Fairness Hearing is April 17, 2017. Plaintiff's counsel will have its Motion for Final Approval filed on or before April 28, 2017. Plaintiff's counsel respectfully suggests that the Court schedule the final fairness hearing for May 12, 2017.

7. Settlement Termination

Either the Defendants or the Plaintiff may terminate the Settlement if the Settlement is rejected or materially modified by the Court or by an appellate court.

8. Class Representative Service Award

Plaintiff's counsel will seek, and the Defendants will not oppose, a service award of \$10,000 for the Plaintiff Shannon Mahoney. If the Court approves the Settlement, the service award will be paid from the Settlement, and will be in addition to the relief the named Plaintiff will be entitled to under the terms of the Settlement. This award will compensate the Plaintiff for her time and effort in the lawsuit, including her time and effort reviewing pleadings, gathering documents, participating in mediation, and staying informed about the litigation.

9. Attorneys' Fees and Costs

Plaintiff's counsel will request attorneys' fees of not more than thirty percent of the Settlement Fund, plus reimbursement of all litigation costs and expenses, which requests the Defendants will not oppose. The Defendants' counsel and Plaintiff's counsel negotiated and reached this agreement regarding attorneys' fees and costs only after reaching agreement on all other material terms of this Settlement.

III. ARGUMENT

A. THE LEGAL STANDARD FOR PRELIMINARY APPROVAL

Rule 23(e) of the Federal Rules of Civil Procedure requires judicial approval for the

compromise of claims brought on a class basis. “The law favors settlements of class actions no less than other cases.” *In re Gulf Oil/Cities Serv. Tender Offer Litig.*, 142 F.R.D. 588, 590 (S.D.N.Y. 1992) (citing *Weonberger v. Kendrick*, 698 F.2d 61, 73 (2d Cir. 1982). “Approval of the Settlement is within the Court’s broad discretion.” *In re American Bank Note Holographics, Inc.*, 127 F.Supp.2d 418, 423-24 (S.D.N.Y. 2001). “The Court must eschew any rubber stamp approval in favor of an independent evaluation, yet, at the same time, it must stop short of the detailed and thorough investigation that it would undertake if it were actually trying the case.” *City of Detroit v. Grinnell Corp.*, 495 F.2d 448, 462 (2d. Cir. 1974), abrogated on other ground by *Goldberger v. Integrated Res., Inc.*, 209 F.3d 43, (2d Cir. 2000). As the Second Circuit in *Grinnell* held:

It is not necessary in order to determine whether an agreement of settlement and compromise shall be approved that the court try the case which is before it for settlement . . . Such procedure would emasculate the very purpose for which settlements are made. The Court is only called upon to consider and weigh the nature of the claim, the possible defenses, the situation of the parties, and the exercise of business judgment in determining whether the proposed settlement is reasonable.

Id. (citing *Newman v. Allen*, 338 F.2d 2 (2d Cir. 1964); see also *Parker v. Anderson*, 667 F.2d 1204, 1209 (5th Cir. 1982) (The “court does not adjudicate the dispute.”). Accordingly, “a court should be mindful of the ‘strong judicial policy in favor of settlements, particularly in the class action context.’” *In re Initial Public Offering Sec. Litig.*, 671 F.Supp.2d 467, 479 (S.D.N.Y. 2009).

“Where the proposed settlement appears to be the product of serious, informed, non-collusive negotiations, has no obvious deficiencies, does not improperly grant preferential treatment to class representative or segments of the class and falls within the reasonable range of approval, preliminary approval is granted.” *In re Nasdaq Antitrust Litig.*, 176 F.R.D. 99, 102 (S.D.N.Y 1997) (citing *Manual for Complex Litigation*, Third, § 20.41 (1995)). Upon preliminary

approval, the Court “must direct the preparation of notice of the certification of the settlement class, the proposed settlement and the date of the final fairness hearing.” *In re IPO Litig.*, 226 F.R.D. 186, 191 (S.D.N.Y. 2005). Settlement negotiations that involve arm’s length, informed bargaining with the aid of experienced counsel support a preliminary finding of fairness. *See Manual for Complex Litigation*, Third, § 30.42 (West 1995) (“A presumption of fairness, adequacy, and reasonableness may attach to a class settlement reached in arm’s-length negotiations between experienced, capable counsel after meaningful discovery.”) (internal quotation marks omitted).

“To evaluate whether a class settlement is fair, a district court examines (1) the negotiations that led up to the settlement, and (2) the substantive terms of the settlement.” *Berkson v. Gogo LLC*, 147 F.Supp.3d 123, 131 (E.D.N.Y. 2015). The fairness of the substantive terms of the proposed settlement is governed by the *Grinnell* factors. *Id.* Those factors include: (1) the complexity, expense and likely duration of the litigation; (2) the reaction of the class to the settlement; (3) the stage of the proceedings and the amount of discovery completed; (4) the risks of establishing liability; (5) the risks of establishing damages; (6) the risks of maintaining the class action through the trial; (7) the ability of the defendants to withstand a greater judgment; (8) the range of reasonableness of the settlement fund in light of the best possible recovery; and (9) the range of reasonableness of the settlement fund to a possible recovery in light of all the attendant risks of litigation. *Grinnell*, 495 F.2d at 463. Here, all of the *Grinnell* factors weigh in support of preliminary approval of the Settlement.

B. THIS SETTLEMENT SATISFIES THE CRITERIA FOR PRELIMINARY SETTLEMENT APPROVAL

Each of the relevant *Grinnell* factors supports preliminary approval of this Settlement. First, the Settlement was reached in the absence of collusion, and is the product of good-faith,

informed and extensive arm's length negotiations by competent counsel, in conjunction with an experienced mediator. Furthermore, a preliminary review of the factors related to the fairness, adequacy, and reasonableness of the Settlement demonstrates that preliminary approval is appropriate.

Any settlement requires the parties to balance the merits of the claims and defenses asserted against the attendant risks of continued litigation and delay. The Plaintiff believes that the claims asserted are meritorious and that the Plaintiff would prevail if this matter proceeded to trial. The Defendants deny any potential liability, and have shown a willingness to litigate those claims vigorously. The Plaintiff and the Defendants concluded that the benefits of the Settlement outweigh the risks attendant to continued litigation that include, but are not limited to, class certification, the Second Circuit's potential interlocutory review of any class certification order, the time and expense associated with proceeding to trial, the time and expense associated with appellate review, and the countless uncertainties of litigation.

1. This Settlement Is The Product Of Good Faith, Informed And Arm's Length Negotiations

"[A] strong presumption of fairness attaches to a class action settlement reached in arm's length negotiations among able counsel." *In re Telik, Inc. Sec. Litig.*, 576 F.Supp.2d 570, 576 (S.D.N.Y. 2008). The Settlement here is the result of intensive, long-running, arm's length negotiations between experienced attorneys who are familiar with class action litigation and with the legal and factual issues of this lawsuit. The Defendants' and Plaintiff's counsel engaged in two formal mediations before an experienced and respected mediator, former United States District Court Judge Barbara Jones. Counsel for the parties negotiated this Settlement over a seven-month period spending hundreds of hours of attorney time, which included two all-day mediation sessions with Judge Jones and many telephonic negotiation sessions conducted among counsel both before

and after the sessions with Judge Jones. These negotiations were arm's length and extensive.

Judge Jones' "role in the settlement negotiations strongly supports a finding that they were conducted at arm's-length and without collusion." *See In re Telik Inc. Sec. Litig.*, 576 F.Supp.2d at 576 ("Judge Weinstein's role in the settlement negotiations strongly supports a finding that they were conducted at arm's length and without collusion."); *See In re AMF Bowling Sec. Litig.*, 334 F.Supp.2d 462, 465 (S.D.N.Y. 2004) ("The participation of Judge Sweet and retired Judge Politan in the settlement process gives me confidence that they were conducted in an arms-length, non-collusive manner."); *In re Elan Sec. Litig.*, 385 F.Supp.2d 363, 369 (S.D.N.Y. 2005) ("[T]he Court has no reason to question that the Settlement was the product of extended arm's length negotiations, including, among other things, the two-day settlement conference before Judge Politan."); *In re IPO Sec. Litig.*, 226 F.R.D. 186, 194 & n. 42 (S.D.N.Y. 2005) (where negotiations were facilitated by Judge Politan, settlement was "clearly the result of arm's length bargaining.")). Judge Jones was keen to point out the strengths and weaknesses of each side's case, and did so in detail and with authority. Her ability to deconstruct each side's position had the effect of forcing the parties to take a hard look at the future of this litigation and to weigh that against the merits of settlement. Furthermore, counsel for both sides are particularly experienced in the litigation, certification, trial, and settlement of nationwide class action cases. Plaintiff's counsel and Defense counsel zealously represented their clients in this lawsuit.

In negotiating this Settlement, Plaintiff's counsel had the benefit of receiving damages discovery from the Defendants, including spreadsheets reflecting Tablet sales and revenues by market category and package, among other metrics, which Plaintiff's counsel checked against publicly available data to confirm that the information supplied by Defendants was complete. Plaintiff's counsel's review of the damages documents provided by Defendants enabled Plaintiff's

counsel to gain an understanding of the evidence related to the central questions in the lawsuit, and prepared Plaintiff's counsel for well-informed settlement negotiations. *See Flores v. Mamma Lombardi's of Holbrook, Inc.*, 104 F.Supp.3d 290, 302 (E.D.N.Y. 2015) (holding that plaintiffs had sufficient information to evaluate the strength and weaknesses of the lawsuit where they had conducted interviews and reviewed discovery). Plaintiff's counsel was also well positioned to evaluate the strengths and weaknesses of Plaintiff's claims, as well as the appropriate basis upon which to settle them, as a result of similar class action cases Plaintiff's counsel have brought in the past.

2. The Grinnell Factors Support A Preliminary Determination That The Settlement Is Fair, Adequate, And Reasonable

As noted above, this Court may conduct a preliminary review of the *Grinnell* factors to determine whether the Settlement is fair such that notice and a final hearing as to the fairness, adequacy, and reasonableness of the Settlement is warranted.

(a) The Complexity, Expense, And Likely Duration Of The Litigation

The first *Grinnell* factor weighs in favor of granting preliminary approval of the Settlement. The traditional means for handling claims like those at issue here would tax the court system, require a massive expenditure of public and private resources, and, given the relatively small value of the claims of the individual Class members, be impracticable. Thus, a class action is the best mechanism for adjudicating the Class members' claims. Given the costs and risks of litigation and the years any final resolution of this matter will likely require, the Settlement is the best vehicle for Class members to receive the relief to which they are entitled in a prompt and efficient manner. The expenses required to litigate this case would also be significant.

The Defendants communicated to Plaintiff's counsel that they intended to depose over 50 absent Class members and pharmacists, in addition to the depositions that the Plaintiff would want

to take of the Defendants. The costs associated with these depositions would be substantial. Furthermore, one of the most expensive aspects of ongoing litigation of the lawsuit involves the retention of experts required to rebut the Defendants' claims regarding the potency of the Tablets. While Plaintiff believes that the settlement in the *qui tam* constitutes a binding admission by Defendants, Defendants do not agree, and intended to litigate the issue, including what their label statements meant. Invariably some aspects of this would become battles of experts, including those necessary to substantiate the Class' claim that the Tablets were sub-potent, to explain the manufacturing process and the different types of fluoride, and to calculate the Class' damages on an individual basis. These experts would be required to analyze substantial amounts of data, prepare expert reports, sit for deposition, and testify at trial. These costs would be substantial and would reduce class members' recoveries. *In re The Prudential Ins. Co. of Am. Sales Practices Litig.*, 148 F.3d 283, 318 (3d Cir. 1988) (holding that settlement favored where "the trial of this class action would be a long, arduous process requiring great expenditures of time and money on behalf of the parties and the court.").

By contrast, the Settlement confers an immediate benefit on the Class, whereas continued litigation would have been complex, risky, expensive, and time consuming. The Class faced significant risks at class certification, summary judgment, and trial. Any successful outcome without a settlement would have required additional years of litigation. The Settlement appropriately discounts those risks from the maximum possible recovery. As the Court in *In re American Bank Note Holographics, Inc.* held, "[s]ettlement at this juncture results in a substantial and tangible present recovery, without the attendant risk and delay of trial. This weighs in favor of the proposed Settlement." 127 F. Supp. 2d at 425. Similarly here, settlement at this juncture results in a tangible recovery for the Class with reduced costs and without the attendant delay and

risk associated with additional litigation. *See Slomovics v. All for a Dollar, Inc.*, 906 F. Supp. 146, 149 (E.D.N.Y. 1995) (“The potential for this litigation to result in great expense and to continue for a long time suggest[s] that settlement is in the best interest of the Class.”) These considerations, and the other considerations noted above, militate heavily in favor of the Settlement.

(b) The Reaction Of The Class To The Settlement

Notice to the Class has not yet been approved by this Court and thus Plaintiff’s counsel does not yet know the Class’ reaction to the Settlement. However, the Plaintiff was intimately involved in the litigation and reviewed all of the substantive pleadings in the case, and she believes the Settlement is fair and reasonable. Plaintiff’s counsel will address this factor more thoroughly in its Motion for Final Approval after the Court rules on the motion for preliminary approval and considers the notice program.

(c) The Stage Of The Proceedings And The Amount Of Discovery Completed

Courts consider the stage of proceedings at which settlement is achieved “to assure the Court that counsel for plaintiffs have weighed their position based on a full consideration of the possibilities facing them.” *In re Global Crossing Sec. and ERISA Litig.*, 225 F.R.D. 436, 458 (S.D.N.Y. 2004) (internal quotations and citations omitted). “Formal discovery is not a prerequisite; the question is whether the parties had adequate information about their claims.” *Id.* The Settlement between the parties was reached after seven months of negotiation and after two full days of intense mediation sessions with retired United States Judge Jones. Even though the Court ordered a stay of all discovery in this lawsuit, Defense counsel provided Plaintiff with extensive records related to the volume and sales figures for Defendants’ Tablets. Plaintiff also was able to review a substantial amount of publicly available documentation, including

pharmaceutical databases. Plaintiff's counsel also had the benefit of the *qui tam* settlement, which detailed the conduct at the heart of the Amended Complaint, and thus Plaintiff's counsel had a reasonably detailed idea both of what the evidence would show and what Defendants would argue in response. Informal discovery in this case was therefore substantial. Moreover, with respect to the critical damages issues, Plaintiff's counsel worked with their damages expert, the data supplied by Defendants, and publicly available information, to determine the range of damages available to the Class.

Plaintiff's counsel also benefitted from the substantive legal briefing on Defendants' Motion to Dismiss and the Court's Order on that motion. With regard to class certification, Plaintiff's counsel has handled a number of class action cases in several circuits, both in the trial and appellate courts, and is very familiar with the issues and arguments made by defendants opposing certification, all of which would have been made very effectively here by experienced defense counsel. As a result, Plaintiff's counsel was sufficiently well informed to confidently evaluate the strengths and weaknesses of Plaintiffs' claims and prospects for success at class certification, summary judgment, trial, and on appeal. Accordingly, this *Grinnell* factor weighs in favor of approval of the Settlement.

(d) The Risks Of Establishing Liability

The fourth *Grinnell* factor is the risks that the plaintiff would face in establishing liability if she had to try the lawsuit on the merits. *Grinnell*, 495 F.2d at 463. This factor does not require the court to adjudicate the disputed issues or decide unsettled questions of law; rather, the court need only assess the risks of litigation against the certainty of recovery under the proposed settlement. See *In re Austrian and German Bank Holocaust Litig.*, 80 F. Supp. 2d 164, 176 (S.D.N.Y 2000). Courts have routinely held that this factor weighs in favor of settlement where

“plaintiffs would have faced significant legal and factual obstacles to proving their case.” *In re Global Crossing Secs. And ERISA Litig.*, 225 F.R.D. at 459.

The Plaintiff has taken the position that liability was established given certain admissions by the Defendants in the related *qui tam* settlement. However, Defendants have made colorable arguments as to why those admissions would not be binding and do not establish liability. For example, Defendants still maintain that their disclosures were adequate and put the members of the Class on notice that the labeled fluoride concentration was expressed as sodium fluoride. Plaintiff believes that the evidence is clear, particularly given the reference to the ADA-AAP Guidelines, that the label refers to fluoride ion. But there is always the risk that Defendants could create sufficient doubt in a jury to preclude a verdict for Plaintiff. Furthermore, Defendants intended to attack Plaintiff’s efforts at certification by raising numerous defenses including that Class members knew and understood the representations differently, undermining certification by raising individualized issues. While Plaintiff is confident that she would prevail, given the inherent merits of her case, there were substantial obstacles and risks in certifying a class, defending against Defendants’ motion for summary judgment, and prevailing at trial. Accordingly, this factor weighs in favor of settlement.

(e) The Risks Of Establishing Damages

The fifth *Grinnell* factor addresses the plaintiff’s risk of establishing damages. *Grinnell*, 495 F.2d at 463. Here, the effort to establish the Class’ retail damages was substantial. At the outset, Plaintiff would have had to defend her damages theory. Defendants made it quite clear, throughout the litigation, that while there were numerous different ways to measure damages (retail cost, wholesale costs, profit, reduction in value, etc.), they believed each possessed fatal flaws. After overcoming that hurdle, the Plaintiff would have had to serve and likely litigate

subpoenas on the largest Pharmacy Benefit Management (“PBM”) companies and Third Party Payers (“TPP”). There is no certainty that the various courts with jurisdiction would enforce Plaintiff’s subpoenas that request data from these entities based on NDC numbers for the Tablets. Without this data, it would be more difficult to establish the Class’ damages. And while Plaintiff is certain that it could be done with publicly-available data, there is risk here. With the Settlement, however, these entities are incentivized to provide the data required. Accordingly, this factor weighs in favor of Settlement.

(f) The Risks Of Maintaining The Class Action Through The Trial

Had this case not settled, the Defendants intended to contest class certification on various grounds, thereby creating appreciable risk to the Class members’ potential for recovery. *See, e.g., In re Bleach Sec. Litig.*, No. 94 Civ. 7696, 2002 WL 31720381, at *1 (S.D.N.Y. Dec. 4, 2002). Plaintiff understands that the Defendants intended to argue, for example, that consumers had different understandings about the statements at issue regarding the Tablets’ fluoride content and to attack Plaintiff’s damages model. While the Plaintiff believes that she would have been able to overcome these defenses, they were nonetheless substantial and not frivolous. And even if the Plaintiff successfully certified the Class, there would be a risk of decertification at a later stage either by this Court or the Second Circuit. *See In re NASDAQ Litig.*, 187 F.R.D. at 476-77 (holding that decertification can occur if management problems arise during litigation; decertification or reversal of certification would deprive the class of any recovery). Accordingly, this factor weighs in favor of Settlement and supports a finding that the Settlement was fair.

(g) The Ability Of The Defendants To Withstand A Greater Judgment

The seventh *Grinnell* factor – the Defendants’ ability to withstand a greater judgment – also favors approval of the Settlement. “[T]he fact that a defendant is able to pay more than it

offers in settlement does not, standing alone, indicate that the settlement is unreasonable or inadequate.” *In re PaineWebber Ltd. Partnerships Litig.*, 171 F.R.D. 104, 129 (S.D.N.Y. 1997).

While the Defendants are a multi-national pharmaceutical company, the Defendants’ share price has dropped more than 40% over the past year as it has come under pricing pressure on its generic drugs and has had to settle a number of lawsuits related to other litigation. See <http://www.businessinsider.com/endo-pharmaceuticals-down-40-2016-5> (last accessed Sept. 6, 2016). The payment schedule agreed to is sensitive to the Defendants’ current fiscal reality. As reflected in its share price, the Defendants have lost a substantial amount of market value this year and its financial prospects for fiscal year 2017 are challenging. Accordingly, there is no definitive evidence that the Defendants could sustain a significantly larger judgment.

(h) Range Of Reasonableness In Relation To Potential Recovery

The final two *Grinnell factors* – the reasonableness of the settlement in light of the best possible recovery and the risks of litigation – also weigh heavily in favor of approval of the Settlement. “[T]he fact that a proposed settlement may only amount to a fraction of the potential recovery, does not, in and of itself, mean that the proposed settlement is grossly inadequate and should be disapproved.” *Grinnell*, 495 F.2d at 455; see, e.g., *In re PaineWebber Litig.*, 171 F.R.D. at 130 (holding that fairness determination turns not on a “mathematical equation yielding a particularized sum . . . but rather . . . [on] the strengths and weaknesses of the plaintiff’s case.”) (quotation marks omitted). Thus, courts routinely look to whether the settlement amount falls within the “range of reasonableness.” *Newman v. Stein*, 464 F.2d 689, 693 (2d Cir. 1972). Here, the Settlement falls well within that range of reasonableness as the \$15,500,000 represents approximately half of the revenues earned by the Defendants from their sales of the Tablets.

Furthermore, due to the complexities inherent in this case, this Settlement has to be judged

in the context of the “legal and practical obstacles to obtaining a large recovery.” *In re Global Crossing Sec. Litig.*, 225 F.R.D. at 461. As noted above, there are substantial legal obstacles to Plaintiff’s and the Class’ recovery. While the Plaintiff believes that she would be able to overcome Defendants’ defenses to class certification and summary judgment, those defenses were substantial and posed a threat to any recovery.

(i) The *Grinnell* Factors Support A Preliminary Determination That The Settlement Is Fair

As noted, this Court may conduct a preliminary review of the *Grinnell* factors to determine whether the Settlement is fair such that notice and a final hearing as to the fairness of the Settlement is warranted. When balanced, all of the *Grinnell* factors weigh in favor of a finding that the Settlement is fair and support granting preliminary approval.

C. CERTIFICATION OF THE SETTLEMENT CLASS IS APPROPRIATE

For settlement purposes, the Plaintiff respectfully requests that the Court certify the Class in Section (II)(C)(1). “Confronted with a request for settlement-only class certification, a district court need not inquire whether the case, if tried, would present intractable management problems . . . for the proposal is that there be no trial.” *Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 620 (1997). Certification of the proposed Class will allow notice of the Settlement to issue to inform Class members of the existence and terms of the Settlement. *See Manual for Compl. Lit.* §§ 21.632, 21.633. For purposes of this Settlement only, the Defendants do not oppose class certification. For the reasons set forth below, certification is appropriate under Rule 23(a) and (b)(3).

Certification under Rule 23(a) of the Federal Rules of Civil Procedure requires that (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the

claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class. Under Rule 23(b)(3), certification is appropriate if the questions of law or fact common to the members of the class predominate over individual issues of law or fact and if a class action is superior to other available methods for the fair and efficient adjudication of the controversy. Here, the Class should be certified because it satisfies all of the Rule 23 requirements.

1. The Class Members Are Too Numerous To Be Joined

Plaintiff meets the first requirement of Rule 23(a) because the Class is so numerous that joinder of all members is impracticable. *See Fed. R. Civ. P. 23(a)(1)*. To satisfy the numerosity requirement, “a plaintiff need not show that joinder is impossible. Nor need the plaintiff know the exact number of class members.” *Saddle Rock Partners Ltd. v. Hiatt*, 2000 WL 1182793, at *2 (S.D.N.Y. Aug. 21, 2000) (citations omitted). Rather, while “[t]here is no strict numerical test for determining impracticability of joinder[,] … [w]hen class size reaches substantial proportions … the impracticability requirement is usually satisfied by the numbers alone.” *In re American Med. Sys., Inc.*, 75 F.3d 1069, 1079 (6th Cir. 1996) (citations omitted). There is no “magic minimum number” to establish numerosity. *Gortat v. Capala Bros.*, 949 F. Supp. 2d 374, 383 (E.D.N.Y. 2013). In determining numerosity, courts not only look to the number of persons in a class, but also, among others, to the following considerations: 1) judicial economy arising from the avoidance of multiplicity of actions; 2) geographic dispersion of class members; 3) financial resources of class members; and 4) ability of claimants to institute individual suits. *Id.* (finding that as little as 24 class members may meet the numerously requirement). Here, the Defendants sold millions of Tablets to tens of thousands of Class members in 26 different states. Accordingly, the number of potential Class members coupled with their widely-dispersed locations in the United States makes joinder impracticable and class treatment appropriate.

2. There Are Common Questions Of Fact And Law

The commonality requirement of Rule 23(a) is met if the claims involve questions of law or fact that are common to the class. *See Robinson v. Metro-North Commuter R.R. Co.*, 267 F.3d 147, 155 (2d Cir. 2001). The commonality requirement is satisfied if the named plaintiff shares at least one question of fact or law in common with the class. *See Marisol A. v. Giuliani*, 126 F.3d 372, 376 (2d Cir. 1997).

The Plaintiff and the Class members have numerous issues of law and fact in common, including:

- a. Whether the Defendants' Tablets contained the concentration of fluoride represented on its label and packaging;
- b. Whether the fact that Defendants' Tablets manufactured during the Class period did not contain the labeled concentration of fluoride rendered the vitamins valueless;
- c. Whether the Defendants inappropriately profited from the sale of the Tablets;
- d. Whether the Defendants breached their express warranty with respect to the sale of the Tablets because they did not contain the labeled concentration of fluoride;
- e. Whether Defendants made a series of fraudulent misrepresentations with respect to the Tablets' fluoride content;
- f. Whether the Defendants violated New York General Business Law § 349 by selling Tablets that did not contain the labeled concentration of fluoride; and
- g. Whether the Defendants committed fraud by knowingly selling the Tablets with less fluoride than that stated on the label and package insert during the Class period and by continuing to sell them even after they became aware that the

government was investigating their fluoride content.

These common issues are more than sufficient to satisfy Rule 23(a)(2).

3. The Class Representative's Claims Are Typical

Rule 23(a)(3) requires that “claims or defenses of the representative parties [be] typical of the claims or defenses of the class.” Fed. R. Civ. P. 23(a)(3). Like the test for commonality, “[t]he typicality requirement is ‘not demanding.’” *In re Initial Pub. Offering Sec. Litig. (IPO II)*, 227 F.R.D. 65, 87 (S.D.N.Y. 2004), *vacated on other grounds*, 471 F.3d 24 (2d Cir. 2006) (citations omitted). The typicality requirement is readily met where “the claims of the named plaintiffs arise from the same practice or course of conduct that gives rise to the claims of the proposed class members.” *In re Vivendi Universal S.A.*, 242 F.R.D. 76, 85 (S.D.N.Y. 2007) (internal quotation and citation omitted). There is no requirement, however, that the claims of all members of a proposed class be identical. *In re Marsh & McLennan Cos., Inc. Sec. Litig.*, 2009 WL 5178546, at *10, (S.D.N.Y. Dec. 23, 2009).

The Plaintiff’s claims are typical of the Class members’ claims because of the uniformity of the Defendants’ unlawful conduct. Plaintiff, like all Class members, was damaged through her payment of money for Tablets that Defendants falsely claimed to contain certain concentrations of fluoride ion. Instead, Defendants’ Tablets contained only a sub-therapeutic dose of fluoride ion, rendering them clinically and economically valueless. Each Class member has sustained damages in the same manner as the Plaintiff, as a result of Defendants’ wrongful conduct.

4. The Class Representative Will Fairly And Adequately Protect The Interests Of The Class

Rule 23(a)(4) requires that “the representative parties will fairly and adequately protect the interest of the class.” This requirement is met if it appears that: (1) the named plaintiff’s interests are not antagonistic to the class’ interests; and (2) the named plaintiff’s attorneys are qualified,

experienced, and generally able to conduct the litigation. *See In re Drexel Burnham Lambert Grp.*, 960 F.2d 285, 291 (2d Cir. 1992); *In re Marsh*, 2009 WL 5178546, at *10. Here, Plaintiff and members of the Class are similarly situated because they share the same claims and have the same interest in maximizing the recovery from the Defendants. *See Drexel*, 960 F.2d at 291; *In re Polaroid ERISA Litig.*, 240 F.R.D. 65, 77 (S.D.N.Y. 2006) (no conflict of interest between class representatives and absent class members where they share the common goal of maximizing recovery). The Plaintiff has protected the interests of the Class vigorously and without conflict, and will continue to do so. The Plaintiff and the Class have the same interest in establishing that the Defendants caused or contributed to their damages; therefore, their incentives align perfectly.

Plaintiff's counsel, Buckner + Miles and McCabe Rabin, have extensive experience and expertise in complex litigation and class action proceedings throughout the United States. The lawyers at those firms have recovered more than a billion dollars for their clients and the classes they have represented, and are qualified and able to conduct this litigation. (Ex. 9, Attorney Biographies). Thus, the requirements of Rule 23(a)(4) are satisfied.

5. The Predominance Requirement Of Rule 23(B)(3) Is Satisfied

Rule 23(b)(3) requires that the common questions of law or fact predominate over any questions affecting only individual class members and that a class action be superior to other available methods of adjudication. Both of these requirements are met here.

(a) Common Questions Predominate

Rule 23(b)(3) does not require a complete absence of any individual issues. *See Dura-Bilt Corp. v. Chase Manhattan Corp.*, 89 F.R.D. 87, 99 (S.D.N.Y. 1981) ("To be sure, individual issues will likely arise in this as in all class action cases."). Rather, it requires predominance, which entails that "some of the legal or factual questions" can be resolved through "generalized proof" and that "these particular issues are more substantial than the issues subject only to individualized

proof.” *Moore v. PaineWebber, Inc.*, 306 F.3d 1247, 1252 (2d Cir. 2002) (internal quotation marks omitted). The Supreme Court has defined this inquiry as establishing “whether proposed classes are sufficiently cohesive to warrant adjudication by representation.” *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 623 (1997). This inquiry is “similar” to Rule 23(a)(3)’s typicality requirement. *Id.* at 623 n.18.

This case involves the type of “common nucleus of operative facts and issues with which the predominance inquiry is concerned.” *In re Nassau Cnty. Strip Search Cases*, 461 F.3d 219, 228 (2d Cir. 2006). The proof of any liability on the part of the Defendants would be common to the Class as a whole because it is based on the Defendants’ uniform misrepresentations on the Tablets’ label and packaging inserts and on whether the Tablets actually had the stated fluoride content that Defendants claimed. These facts and issues apply class-wide, making class-wide proof the overriding focus of any trial of this case.

Furthermore, numerous claims remained after the Court entered its Order on Defendants Motion to Dismiss. [D.E. 78]. The Plaintiff’s breach of express warranty, N.Y.G.B.L. § 349, fraud, and fraudulent misrepresentation remained and were viable. With the exception of the § 349 claim, any of those claims could have been certified on a nationwide basis. *See Ebin v. Kangadis Food Inc.*, 297 F.R.D. 561, 569-70 (S.D.N.Y. 2014). Plaintiff’s fraud claims were appropriate for certification because they were based on uniform misrepresentations made by Defendants on their product label and the packaging insert. This comports with the Second Circuit’s holding in *Moore v. Painewebber, Inc.*, 306 F.3d 1247, 1253 (2nd Cir. 2002), where the court held:

Fraud actions must therefore be separated into two categories: fraud claims based on uniform misrepresentations made to all members of the class and fraud claims based on individualized misrepresentations. The former are appropriate subjects of

class certification because the standardized misrepresentations may be established by generalized proof.

Applying this rationale, the Court in *Ebin* held with respect to the class' fraud and fraudulent misrepresentation claims, "a survey of potentially applicable state laws reveals no material difference that would affect the merits of the class's common law claims at trial; elements of the common law of fraud are sufficiently similar across jurisdictions where [the product] was sold." *Id.* at 570. In so holding, the Court in *Ebin* explained:

Although certain courts have held that cases which implicate the common law of fraud are inappropriate for class resolution . . . this is not true in this instance, the item purchased, by labeling itself as 100% Pure Olive Oil, in effect defined the product. Unlike most fraud and negligent misrepresentation claims, it is thus inconceivable that any individual would not have relied on the tin's labeling in its purchase, since otherwise the individual would merely be purchasing a random tin of unknown fluid. Thus, the Court finds that while some variation among states in the common law fraud and negligent misrepresentation, when applied to the facts of this particular case any such variation is unlikely to lead to actual variation in adjudication of liability.

Ebin v. Kangadis Family Management, LLC., 45 F.Supp.3d 395, 399 (S.D.N.Y. 2014). Relying on *Ebin*, the Court in *Rodriguez v. It's Just Lunch, Intern.*, 300 F.R.D. 125, 140 (S.D.N.Y. 2014), rejected the argument that potential variations in state laws prohibited nationwide certification of fraud claims where the proof of Defendants' scienter could be established from common evidence. "The scienter element of states' fraud laws fall into such limited patterns . . . The variations in state fraud scienter requirement therefore do not create individual issues that predominate over common ones with respect to the fraud claims of the proposed national class." *Id.* As in *Ebin* and *Rodriguez*, the Tablets were defined by the label and package insert that represented that they contained a certain amount of fluoride ion, and it is inconceivable that any member of the Class would purchase the Tablets without relying on the Tablets' labeling. Plaintiff and the Class' claim could be proven utilizing common proof based on the misrepresentations made on the package labeling and

package insert compared to Defendants' master formula, which affirmatively demonstrates that the stated amount of fluoride ion in the Tablets was not present. Accordingly, the predominance requirement is satisfied.

(b) A Class Action Is The Superior Method Of Adjudication

Rule 23(b)(3) also sets forth the following non-exhaustive factors to be considered in making a determination of whether class certification is the superior method of litigation: "(A) the class members' interests in individually controlling the prosecution ... of separate actions; (B) the extent and nature of any litigation concerning the controversy already begun by ... class members ...; and (D) the likely difficulties in managing a class action." Fed. R. Civ. P. 23(b)(3). Considering these factors, proceeding by means of a class action is clearly "superior to other available methods for fairly and efficiently adjudicating" the potential claims against the Defendants. *Id.*

The high cost of individualized litigation of Plaintiff's claims against the Defendants makes it unlikely that the vast majority of the Class members would be able to pursue their own potential claims and obtain relief without class certification. This is particularly true because most Class members have claims that are too small to adjudicate individually. Plaintiff, for example, had out of pocket expenses of approximately \$300 for the purchase of the Tablets, not including the payments made by her insurance company. The costs to litigate this case would far exceed any recovery she would be entitled to obtain if her claim was litigated on an individual basis. Separate actions would also "risk disparate results among those seeking redress, ... encourage a race to judgment given the limited funds available to fund recovery here, ... exponentially increase the costs of litigation for all, and ... be a particularly inefficient use of judicial resources." *Cromer Fin. Ltd. v. Berger*, 205 F.R.D. 113, 133 (S.D.N.Y. 2001) (footnote omitted). Similarly, no other Class members have filed lawsuits related to the Tablets. Thus, there is no manifest interest by

any other Class members in pursuing their own lawsuits regarding these claims. Finally, there are no difficulties in managing this case as a class action.

D. THE FORM OF NOTICE AND NOTICE PROGRAM SHOULD BE APPROVED

“Rule 23(e)(1)(B) requires the court to direct notice in a reasonable manner to all class members who would be bound by a proposed settlement, voluntary dismissal, or compromise regardless of whether the class was certified under Rule 23(b)(1), (b)(2), or (b)(3).” Manual for Compl. Lit. § 21.312 (internal quotation marks omitted). The best practicable notice is that which is “reasonably calculated, under all the circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections.” *Mullane v. Cent. Hanover Bank & Trust Co.*, 339 U.S. 306, 314 (1950). To satisfy this standard, the Second Circuit has held that the adequacy of a class action settlement notice is “measured by reasonableness.” *Masters v. Wilhelmina Model Agency, Inc.*, 473 F.3d 423, 438 (2d Cir. 2007). The Second Circuit in *Masters* noted “[t]here are no rigid rules to determine whether a settlement notice to the class satisfies constitutional or Rule 23(e) requirements; the settlement notice must fairly apprise the prospective members of the class of the terms of the proposed settlement and of the options that are open to them in connection with the proceedings. Notice is adequate if it may be understood by the average class member.” *Id.* (Internal citations omitted.)

Furthermore, where “the parties seek simultaneously to certify a settlement class and to settle a class action, the elements of Rule 23(c) notice (for class certification) are combined with the elements of Rule 23(e) notice (for settlement or dismissal).” *In re Global Crossing Sec. and ERISA Litig.*, 225 F.R.D. at 448. Rule 23(c)(2) requires the “best notice that is practicable,” while Rule 23(e) requires notice that is “reasonably calculated, under all of the circumstances, to apprise interested parties of the pendency of the settlement proposed and to afford them an opportunity to

present their objections.” *In re Prudential Ins. Co. of Am. Sales Practices Litig.*, 962 F. Supp. 450, 527 (D.N.J. 1997), *aff’d*, 148 F.3d 283 (3d Cir. 1998). Neither Rule 23 nor due process requires actual notice to each possible class member. See *In re Marsh*, 2009 WL 5178546, at *23-24; *Buxbaum v. Deutsche Bank AG*, 216 F.R.D. 72, 80-81 (S.D.N.Y. 2003).

The Notice Program satisfies all of these criteria. As recited in the Settlement and above, the Notice Program seeks to identify as many Class members as possible and to provide direct mailed notice to them, informing them of the substantive terms of the Settlement. It advises Class members of their options for opting out of, or objecting to, the Settlement, how to obtain additional information about the Settlement, and how to file a claim. The notice program is designed to reach a high percentage of Class members and it exceeds the requirements of Constitutional due process. Therefore, the Court should approve the notice program and the form and content of the notices attached to this Motion as Exhibits 2 - 8.

E. THE COURT SHOULD SCHEDULE A FINAL APPROVAL HEARING

The last step in the Settlement approval process is a Final Approval Hearing, at which the Court will hear the evidence and argument necessary to make its final evaluation of the Settlement. Proponents of the Settlement may explain the terms and conditions of the Settlement, and offer argument in support of Final Approval. The Court will determine at or after the Final Approval Hearing whether the Settlement should be approved; whether to enter a Final Approval Order under Rule 23(e); and whether to approve Class counsel’s application for attorneys’ fees and reimbursement of costs and expenses. The Plaintiff and Plaintiff’s counsel request that the Court schedule the Final Approval Hearing at the time it enters its Order on Preliminary Approval to allow for that information to be included in the notices. Plaintiff’s counsel respectfully suggests that the Final Fairness Hearing be scheduled for May 12, 2017.

IV. CONCLUSION

Based on the foregoing, the Plaintiff respectfully requests that the Court: (1) grant preliminary approval of the Settlement; (2) certify for settlement purposes the proposed Class, pursuant to Rule 23(b)(3) and (e) of the Federal Rules of Civil Procedure; (3) approve the notice program set forth in the Agreement and approve the form and content of the notices, attached to this Motion as Exhibits 2-8; (4) appoint as the settlement class representative Ms. Mahoney, who is currently the named Plaintiff; (5) appoint as Settlement Class Counsel David M. Buckner, Seth E. Miles, and Brett E. von Borke of Buckner + Miles and Ryon McCabe and Robert C. Glass of McCabe Rabin; and (6) schedule a Final Approval Hearing at the time the Order on Preliminary Approval is entered so that the Final Approval Hearing date can be included in the notice.

Dated: October 21, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on October 21, 2016 the foregoing document was served via the Court's CM/ECF portal to all counsel of records identified on the attached Service List.

/s David M. Buckner
David M. Buckner

SERVICE LIST

Shannon Mahoney

v.

Endo Health Solutions, Inc., et al.

U.S. District Court, Southern District of New York

No. 15-09841-CIV-DLC

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